



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2015

Elizabeth Greene
Director of Quality Assurance and Regulatory Affairs
Stimwave Technologies Incorporated
420 Lincoln Road, Suite 365
Miami Beach, FL 33139

Re: K150517

Trade/Device Name: Freedom Spinal Cord Stimulator (SCS) System
Regulation Number: 21 CFR 882.5880
Regulation Name: Stimulator, Spinal-Cord, Implanted (Pain Relief)
Regulatory Class: Class II
Product Code: GZB
Dated: February 27, 2015
Received: March 2, 2015

Dear Ms. Greene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Indications For Use:

The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The Freedom-8A Trial Lead Kit is only used in conjunction with the Freedom-8A Stimulator Receiver Kit, and the Freedom-4A Trial Lead Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-8A Stimulator. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary
for
Freedom Spinal Cord Stimulator (SCS) System

1. Submission Sponsor

Stimwave Technologies Incorporated
901 East Las Olas Boulevard
Suite 201
Fort Lauderdale
Florida 33301
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Director of Quality Assurance and Regulatory Affairs

2. Date Prepared

February 27, 2015, updated June 1, 2015

3. Device Identification

Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Classification Regulation:	882.5880
Product Code:	GZB
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

Stimwave Freedom SCS System FRE4-A001, FRT4-A001, WAA-A012 (K141399)
Medtronic Mattrix 3271/3272 Neuromodulation System (K934065)
Medtronic Xtrel, Model Number 3425 Receiver (K883780)
ANS Renew Neurostimulation System Transmitter, Model 2508, Receiver Model 3408,
Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186,
Extension Models 3382, 3383, 3341, 3342 and 3343 (K000852)

5. Device Description

The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord SCS System (System) is used for spinal column neural stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or lower limbs including unilateral or bilateral



pain. The therapy utilizes pulsed electrical current to create an electrical energy field that acts on nerves near the dorsal column of the spine. The System is comprised of an implantable stimulator (Freedom-8A/4A Stimulator) and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device. The System is implanted only following a successful trial period with the Freedom-8A/4A Trial Lead.

Freedom-8A and Freedom-4A Stimulator (Receiver Kit)

Freedom-8A Stimulator, Freedom-4A Stimulator	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed in the patient's epidural space. The Freedom-8A Stimulator has eight (8) electrodes, and the Freedom-4A Stimulator has four (4) electrodes.
Stylet(s)	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Two (2) stylets are provided in the Receiver Kit, one straight and one bent, each with diameter of 0.25 mm.
Needle and Cannula Assembly	An assembly that includes a 16-gauge stainless steel needle that is packaged inserted in the fluorinated ethylene propylene (FEP) Cannula that acts as a conduit for passage of the Stimulator into the epidural space.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator to pass through more easily.
Suture Sleeve Cap	A polyurethane (Pellethane 55D) cap that is placed over the proximal end of the Stimulator. The Suture Sleeve Cap is attached to the Freedom-8A/4A Stimulator and can be sutured to tissue to reduce the possibility of device migration.

Wearable Antenna Assembly (WAA Kit)

WAA	<p>The WAA housing includes the following components:</p> <ul style="list-style-type: none">i. <u>Transmitting (Tx) Antenna</u> – Antenna used to transmit microwave energy to the implanted Stimulator;ii. <u>Microwave Field Stimulator (MFS)</u> – A printed circuit board (PCB) that generates 915 MHz RF power with embedded waveform parameter settings and switches for changing parameter settings as needed by the user;iii. <u>Button Cover</u> – A silicon pad that corresponds to switches on the MFS that allows the user to turn the device on/off or increase or decrease power amplitude as well as interpret device power status (On, Off, Charging, Transmitting, and Bluetooth® Connection);iv. <u>Battery Assembly</u> – A battery and wire assembly coupled with the Wireless Charging Coil Assembly for charging and the MFS for power delivery;v. <u>Wireless Charging Coil Assembly</u> – Consists of an inductive
-----	--

Wearable Antenna Assembly (WAA Kit)

	charging coil and battery that receives energy from the Wireless Battery Charging Pad. The battery charger components on the MFS are used to transfer charge into the 3.7V lithium ion battery by facilitating power transfer and warns the system when battery power is low.
Wireless Battery Charging Pad	An off-the-shelf Qi-compliant charging pad (RP-WCN7, RP-WCN12, or RP-WCN13) that uses inductive charging technology to recharge the encased lithium ion battery of the WAA.
Athletic Pouch Belt	An off-the-shelf assembly constructed of lightweight nylon mesh with an adjustable belt, and a zipper pouch for housing the WAA.

Freedom-8A and Freedom-4A Trial Lead (Trial Lead Kit)

Freedom-8A Trial Lead, Freedom-4A Trial Lead	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed percutaneously in the patient's epidural space. The Freedom-8A Trial Lead has eight (8) electrodes, and the Freedom-4A Trial Lead has four (4) electrodes.
Stylet(s)	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Two (2) stylets are provided in the Trial Lead Kit, one straight and one bent with a diameter of 0.25 mm.
Needle and Cannula Assembly	An assembly that includes a 16-gauge stainless steel needle that is packaged inserted in the fluorinated ethylene propylene (FEP) Cannula that acts as a conduit for passage of the stimulator into the epidural space.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Trial Lead to pass through more easily.

6. Indication for Use Statement

The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The Freedom-8A Trial Lead Kit is only used in conjunction with the Freedom-8A Stimulator Receiver Kit, and the Freedom-4A Trial Lead Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-8A Stimulator. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

7. Substantial Equivalence Discussion

The following table compares the Stimwave Freedom SCS System to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence. Stimwave physically measured Medtronic and ANS predicate devices to obtain the values listed in Table 5A.

Table 5A. Comparison of Characteristics

Comparator	Stimwave Freedom SCS System	Stimwave Freedom SCS System (K141399)	Medtronic Matrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Product Code	GZB	GZB	GZB and GZF	GZB	GZB
Regulation No.	882.5880	882.5880	882.5880	882.5880	882.5880
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Implant Site	Epidural space, L5 to T5	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Environmental Use	Hospital, Home	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Intended User	Layperson	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Electrode Material	Platinum-iridium 90:10	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Stimulator Body Material	Polyurethane 2363-55D	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Cable Features	Multi-lumen Tube	Multi-lumen Tube	Coiled Wires	Coiled Wires	Braided Wire
Stimulator Length	45 centimeters	45 centimeters	30 to 110 centimeters	30 to 110 centimeters	30 and 60 centimeters
Diameter	1.35 millimeters	1.35 millimeters	1.3 millimeters	1.3 millimeters	1.37 millimeters
Electrode Array Length	24.0 millimeters 52.0 millimeters	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
No. of Electrodes	4 or 8	4	4	4	4 or 8
Electrode Length	3.0 millimeters	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Electrode Spacing	4.0 millimeters	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Electrode Surface Area	12.72 mm ²	12.72 mm ²	12.25 mm ²	12.25 mm ²	“Approx. 13 mm ² ”
Method of Introduction	Percutaneous and Anchor Incision	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Tissue Contact	Yes	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom



Stimwave Technologies Incorporated
Special 510(k) Premarket Submission
Freedom Spinal Cord Stimulator (SCS) System

Comparator	Stimwave Freedom SCS System	Stimwave Freedom SCS System (K141399)	Medtronic Matrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Sterilization	Ethylene Oxide (EO)	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Package	Backer card and two sterile pouches	Blister Tray/Tyvek Lid	Same as Freedom	Same as Freedom	Same as Freedom
Pulse Frequency	5 to 1500 Hertz	2 to 1500 Hertz	5 to 240 Hertz	5 to 1400 Hertz	10 to 1500 Hertz
Pulse Width	50 to 500 microseconds	50 to 500 microseconds	50 to 500 microseconds	50 to 1000 microseconds	50 to 500 microseconds
Current/Voltage Regulated	Current	Current	Voltage	Voltage	Current
Output Voltage (300 Ω)	0 to 4.1 V	0 to 6.3 V	0 to 7 V	0 to 5.4 V	0 to 5.7 V
Output Voltage (500 Ω)	0 to 6.4 V	0 to 7.2 V	0 to 10.8 V	0 to 7.1 V	0 to 7.6 V
Output Voltage (800 Ω)	0 to 7.5 V	0 to 8.0 V	0 to 11.6 V	0 to 8.4 V	0 to 9.6 V
Output Current (300 Ω)	0 to 13.5 mA	0 to 21 mA	0 to 23.3 mA	0 to 18.0 mA	0 to 19.0 mA
Output Current (500 Ω)	0 to 12.8 mA	0 to 15 mA	0 to 21.6 mA	0 to 14.2 mA	0 to 15.2 mA
Output Current (800 Ω)	0 to 9.4 mA	0 to 10 mA	0 to 14.5 mA	0 to 10.5 mA	0 to 12.0 mA
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical
Pulse Shape	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential
Average Current Density (300 Ω)	105.0 mA/cm ²	111.6 mA/cm ²	175.0 mA/cm ²	125.8 mA/cm ²	117.7 mA/cm ²
Average Current Density (500 Ω)	95.1 mA/cm ²	96.7 mA/cm ²	151.7 mA/cm ²	101.7 mA/cm ²	103.1 mA/cm ²
Average Current Density (800 Ω)	69.0 mA/cm ²	77.0 mA/cm ²	106.7 mA/cm ²	75.8 mA/cm ²	86.2 mA/cm ²
Maximum Phase Charge* (300 Ω)	6.8 μ C/pulse	10.5 μ C/pulse	11.7 μ C/pulse	18.0 μ C/pulse	9.5 μ C/pulse
Maximum Phase Charge* (500 Ω)	6.4 μ C/pulse	7.2 μ C/pulse	10.8 μ C/pulse	14.2 μ C/pulse	7.6 μ C/pulse
Maximum Phase Charge* (800 Ω)	4.7 μ C/pulse	5.0 μ C/pulse	7.3 μ C/pulse	10.5 μ C/pulse	6.0 μ C/pulse
Maximum Charge Density* (300 Ω)	53.1 μ C/cm ²	82.5 μ C/cm ²	97.2 μ C/cm ²	150.0 μ C/cm ²	73.1 μ C/cm ²
Maximum Charge Density* (500 Ω)	50.3 μ C/cm ²	56.6 μ C/cm ²	90.0 μ C/cm ²	118.3 μ C/cm ²	58.5 μ C/cm ²
Maximum Charge Density* (800 Ω)	36.9 μ C/cm ²	39.3 μ C/cm ²	60.4 μ C/cm ²	87.5 μ C/cm ²	46.2 μ C/cm ²
Maximum Current Density* (300 Ω)	106.1 mA/cm ²	165.1 mA/cm ²	194.4 mA/cm ²	150.0 mA/cm ²	146.2 mA/cm ²
Maximum Current Density* (500 Ω)	100.6 mA/cm ²	113.2 mA/cm ²	180.0 mA/cm ²	118.3 mA/cm ²	116.9 mA/cm ²



Stimwave Technologies Incorporated
Special 510(k) Premarket Submission
Freedom Spinal Cord Stimulator (SCS) System

Comparator	Stimwave Freedom SCS System	Stimwave Freedom SCS System (K141399)	Medtronic Matrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Maximum Current Density* (800 Ω)	73.9 mA/cm ²	78.6 mA/cm ²	120.8 mA/cm ²	87.5 mA/cm ²	92.3 mA/cm ²
Net Charge	0 μ C	0 μ C	0 μ C	0 μ C	0 μ C
Average Phase Power (300 Ω)	0.053 W/phase	0.060 W/phase	0.132 W/phase	0.068 W/phase	0.070 W/phase
Average Phase Power (500 Ω)	0.073 W/phase	0.076 W/phase	0.166 W/phase	0.074 W/phase	0.090 W/phase
Average Phase Power (800 Ω)	0.062 W/phase	0.060 W/phase	0.131 W/phase	0.066 W/phase	0.100 W/phase
Average Phase Power Density (300 Ω)	0.42 W/cm ² /phase	0.48 W/cm ² /phase	1.10 W/cm ² /phase	0.57 W/cm ² /phase	0.54 W/cm ² /phase
Average Phase Power Density (500 Ω)	0.58 W/cm ² /phase	0.59 W/cm ² /phase	1.38 W/cm ² /phase	0.62 W/cm ² /phase	0.69 W/cm ² /phase
Average Phase Power Density (800 Ω)	0.48 W/cm ² /phase	0.60 W/cm ² /phase	1.09 W/cm ² /phase	0.55 W/cm ² /phase	0.77 W/cm ² /phase
Pulse Delivery Mode	Continuous	Continuous	Continuous	Continuous	Continuous
ON/OFF Times	No Cycling	No Cycling	ON/OFF Cycling Option	ON/OFF Cycling Option	No Cycling
Current Path Options	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar
Power Delivery	Coupled receiver, built into Stimulator body	Coupled receiver, built into Stimulator body	Coupled receiver, Radio Frequency transmission	Coupling receiver, Radio Frequency transmission	Coupled receiver, hardwired with connector
Transmit Frequency	915 MHz	915 MHz	2 MHz	1.60 MHz	2 MHz
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Sterile	Yes - ethylene oxide	Same as Freedom	Same as Freedom	Same as Freedom	Same as Freedom
Single-Use	Yes	Yes	Yes	Yes	Yes
Shelf Life	2 year	1 year	1 year	1 year	2 years
Complies with ISO 10993-1	Yes	Yes	Yes	Yes	Yes
Safety Testing Passed	Yes	Yes	Yes	Yes	Yes

(*) asterisk denotes that formulas were used for the calculations.

Table 5B identifies the differences between the cleared Freedom SCS System (K141399) and the modifications identified by this Special Premarket Notification.

Table 5B. Comparison of the similarities and differences between FDA-cleared Stimwave product (Freedom-4) and the products submitted in this Special Premarket Notification (Freedom-8A/4A).

Criteria	Freedom-4	Freedom-4A	Freedom-8A
Product Code	GZB	Same as Freedom-4	Same as Freedom-4
Regulation No.	882.5880	Same as Freedom-4	Same as Freedom-4



Stimwave Technologies Incorporated
Special 510(k) Premarket Submission
Freedom Spinal Cord Stimulator (SCS) System

Criteria	Freedom-4	Freedom-4A	Freedom-8A
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as Freedom-4	Same as Freedom-4
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as Freedom-4	Same as Freedom-4
Mode of Action	RF wireless transmission of energy to produce therapeutic stimulation at the Stimulator. The external unit of the system, the WAA, sends a pulsed RF signal on a carrier frequency of 915 MHz to a passive, implanted receiver within the Stimulator	Same as Freedom-4	Same as Freedom-4
No. of Electrodes	4	4	8
MRI Conditional	1.5 and 3T (Receiver Only)	No, MR Unsafe	No, MR Unsafe
Electrode Material	Platinum-Iridium 90:10	Same as Freedom-4	Same as Freedom-4
Stimulator Body Material	Polyurethane 2363-55D	Same as Freedom-4	Same as Freedom-4
Polarity	Fixed	Programmable (Anode, Cathode, or Off)	Programmable (Anode, Cathode, or Off)
Packaging	Blister Tray/Tyvek Lid	Backer card and two Tyvek sterile pouches	Backer card and two Tyvek sterile pouches
Sterilization	Ethylene Oxide (EO)	Same as Freedom-4	Same as Freedom-4
Accessories	Guidewire, Stylet(s), Introducer Sheath, Tuohy Needle, Suture Sleeve Cap	Guidewire, Stylet(s), Coude Needle, Cannula, Suture Sleeve Cap	Guidewire, Stylet(s), Coude Needle, Cannula, Suture Sleeve Cap
Pulse Frequency	2 to 1500 Hz	5 to 1500 Hz	5 to 1500 Hz
Pulse Width	50 to 500 μ s	Same as Freedom-4	Same as Freedom-4
Output Current (500 Ω)	0 to 15 mA	0 to 12.8 mA	0 to 12.8 mA
Transmit Frequency	915 MHz	Same as Freedom-4	Same as Freedom-4
Power Delivery	Coupled receiver, built into Stimulator body	Same as Freedom-4	Same as Freedom-4
Wearable Antenna Assembly (WAA)	Thermoplastic urethane molded wearable transmitter	ABS plastic transmitter contained in a wearable athletic pouch belt	ABS plastic transmitter contained in a wearable athletic pouch belt
iPad Application	Malibu™	WaveCrest™	WaveCrest™
Software Level of Concern	Moderate	Same as Freedom-4	Same as Freedom-4

8. Biocompatibility Data

The materials of the Freedom SCS System (Freedom-8A/4A) remain unchanged from the Freedom SCS System (K141399) and thus, the biocompatibility tests conducted on representative subassemblies of the Freedom SCS System (Freedom-4, K141399) directly apply to the Freedom SCS System (Freedom-8A/4A). The materials, construction and

intended use of the Freedom-8A/4A SCS System is comparable to the predicate device, and have a long history of safety with respect to biocompatibility. The biological safety of the Freedom-8A/4A Stimulator (same as the Freedom-4 Stimulator) was evaluated in accordance to ISO 10993-1:2009 and guidance document Blue Book Memorandum G95-1 *Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, the device was classified as a (C), implant device in contact with tissue/bone. The results for the biocompatible testing for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation (4, 8, and 13 weeks), and subchronic toxicity demonstrated no negative impacts from the materials that are used in the Freedom SCS System. The Freedom-8A/4A Stimulator materials in direct tissue contact include Pellethane 55D and Pt-Ir (90:10), both having an extensive record (previously cleared and approved) of chronic and carcinogenetic safety. The WAA is intended to be on top of a thin shirt or article of clothing around the midsection of the patient. The User Manual provided to the patient describes that the WAA should always be worn on top of a layer of clothing. The WAA does not come into contact with the patient's skin. The categorization by nature of body contact of the WAA is thus "non-contacting device", and not included in the scope of ISO 10993-1:2009. The Freedom-8A/4A SCS System (same as the Freedom SCS System, K141399) meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

The Freedom SCS System was tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The Freedom-8A/4A SCS System complies with all design requirements and applicable voluntary standards.

AAMI ANSI ISO 14708-3:2008 – For protection from temperature change including shipping and storage temperature ranges, the Freedom-8A/4A Stimulator was functional, receiving a safe rating following post visual inspection and passed the change of temperature testing performed as specified by AAMI ANSI ISO 14708-3:2008. For atmospheric pressure change, the Freedom-8A/4A Stimulator was functional following post testing functionality inspection and passed atmospheric pressure change testing as specified by AAMI ANSI ISO 14708-3:2008.

For testing external defibrillation exposure, the Freedom-8A/4A Stimulator was verified as functional after exposure to external defibrillation. Thus, the Freedom-8A/4A Stimulator complies with testing as specified by AAMI ANSI ISO 14708-3:2008

Following the thermal shock testing, the Freedom-8A/4A Stimulator was found to have "no irreversible damage" and fully functional as specified by the manufacturer, and to have no physical anomalies present at the time of inspection. Thus, the Freedom-8A/4A Stimulator complies with the thermal shock design requirements and the applicable standard.

For leakage current testing, the Freedom-8A/4A Stimulator produced zero leakage current on all tested paths for all tested samples. Thus, the Freedom-8A/4A Stimulator complies with the leakage design requirements and the applicable standard.

For testing the insertion and withdrawal of the stimulator within the stylet, the Freedom-8A/4A Stimulator was found to require less than 2.5N of insertion or withdrawal force for all tested stylets in all tested stimulator samples. Visual inspection confirmed no damage was present in any stimulator samples. Thus, the Freedom-8A/4A Stimulator complies with design specifications for stylet insertion and withdrawal force.

For mechanical testing, the Freedom-8A/4A Stimulator passed all criteria of the test, showing no visible damage to the stimulator body or functional damage to the components. Mechanical testing included tensile testing, flex testing and torsion testing. Thus, the Freedom-8A/4A Stimulator complies with all stimulator mechanical design requirements.

IEC 60601-1 – For testing the external unit for protection from temperature change, including shipping and storage temperature ranges, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the external unit of the Freedom SCS System satisfies the outlined protection from temperature change design requirements and the applicable standard, IEC 60601-1. For atmospheric pressure change testing, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the external unit of the Freedom SCS System satisfies the outlined atmospheric pressure change design requirements and the applicable standard, IEC 60601-1. For the push, drop, impact and mold stress relief testing of the external unit, it was determined through testing that the external unit is robust to withstand expected damage in accordance with general safety standards. The external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom-8A/4A SCS System satisfies the outlined push, drop, impact, and mold stress relief design requirements and the applicable standard, IEC 60601-1. For the identification, marking and documents of the external unit it was determined through an analysis of the labeling that the external unit complies with the requirements of the standard. All requirements and markings are clearly identified and viewable either from the external case of the product or from within the accompanying documents. For the means of protection, creepage distances, and air clearances of the external unit it was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1.

IEC 60529 – For testing the ingress of water, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom SCS



System satisfies the outlined Ingress of Water design requirements and the applicable standard IEC 60529. For particulate matter testing, the external unit met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the WAA component of the Freedom SCS System satisfies the outlined Particulate Matter design requirements and the applicable standard, IEC 60529.

IEC 60601-1-2 – For testing the external unit for electromagnetic compatibility, the unit met all acceptance criteria for emissions, low-frequency magnetic fields, immunity, electrostatic discharge, radiated RF electromagnetic fields, electrical fast transients and bursts, and magnetic fields. The external unit operated within all test limits and showed no physical damage and was fully operational. Thus, the external unit for the Freedom-8A/4A SCS System satisfies the IEC 60601-1-2 standard.

The Freedom SCS System complies with the applicable standards for neurostimulators, MRI exposure, electrical safety, electromagnetic interference and compatibility, biocompatibility, packaging, and sterilization. The software of the Freedom SCS System passed all verification tests outlined and the design requirements for Software Verification have been met. The device passed all the testing in accordance with national and international standards.

Following performance testing, it has been determined that the Freedom SCS System is substantially equivalent to legally marketed predicate devices for the therapy for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

Stimwave Technologies Incorporated completed a number of tests for the Freedom SCS System that demonstrates substantial equivalence to the legally marketed predicate devices. The Freedom SCS System meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The Freedom SCS System passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

There was no clinical testing required to support the medical device, as the indications for use are equivalent to the legally marketed predicate devices. These types of devices, including the legally marketed predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to legally marketed predicate devices when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The Freedom SCS System has the same intended



use as the legally marketed predicate devices and is implanted percutaneous into the epidural space ranging from T5 to L5. Performance tested verified that the Freedom SCS System complies with all applicable voluntary standards such as IEC 60601-1, AAMI ANSI ISO 14708-3, and IEC 60529. The Freedom SCS System also meets the design requirements where no applicable standard could be used. This included stimulator body durability testing, programmable parameters, as well as power and performance of the external unit. There were no recognized performance standards for this device. There was no clinical testing performed on this device since performance testing demonstrated similar performance as the legally marketed predicate devices, and materials for the implanted stimulator are the same as the legally marketed predicate devices.

It has been shown in this 510(k) submission that the difference between the Freedom SCS System and the legally marketed predicate devices do not raise any questions regarding its safety and effectiveness as compared to legally marketed predicate devices. Freedom SCS System, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate devices.